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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,418	02/11/2004	Ramachandran Radhakrishnan	LEXOR8.004AUS	2406
20995 7590 01/16/2007 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			EXAMINER MERCIER, MELISSA S	
			ART UNIT 1615	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE	DELIVERY MODE	
3 MONTHS		01/16/2007	ELECTRONIC	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 01/16/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/776,418

Applicant(s)

RADHAKRISHNAN ET AL.

Examiner

Melissa S. Mercier

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 5-24-06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-26 are pending in this application. Claims 1-26 are rejected.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on May 24, 2006 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 10-12, 14, and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "hot", "cold", and "lukewarm" in claims 2, 11, 14, and 25 are relative terms, which render the claim indefinites. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Regarding claims 10-12, it is unclear whether the composition inside the delivery system is a soft gelatin composition or if the delivery system itself is a soft gelatin capsule. Also unclear is what the shell composition comprises, as no limitations are presented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 10-18, and 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Rouffer (US Patent 6,221,391).

Rouffer discloses ibuprofen encapsulated in a soft gelatin capsule (abstract). It is further discloses, "gelatin capsule formulations for soft gelatin capsules consist of raw gelatin and one or more ingredients which are added to plasticize the gelatin to produce a capsule to suitable hardness as required by design or by preference. Typical plasticizers include glycerin and sorbitol. Also, soribitan anhydrides and mannitol may also be utilized. Furthermore, other non-traditional ingredients may be used to plasticize the gelatin such as polyethylene glycol 200 (PEG 200)" (column 4, lines 25-32). According to Rouffer's gelatin formulation "gelatin in the range of approximately 40% to approximately 48% and a plasticizer ranging in amount from approximately 20% to approximately 35%" (column 4, lines 42-47).

Rouffer additionally discloses dissolution profiles for the gelatin capsules utilizing USP apparatus #2, paddle, at 100RMP and a dissolution medium of water at 37C (Example 10).

Claims 10-12, 23-24 and 26 rejected under 35 U.S.C. 102(b) as being anticipated by Clemente et al. (WO 00/13678).

Clemente discloses a gelatin capsule containing an extended release acetaminophen composition, which when assayed according to USP Apparatus 1 rotating basket at 50rpm in 900mL of phosphate buffer at 37C dissolves (abstract).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

Art Unit: 1615

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 7-8 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rouffer (US Patent 6,221,391) in view of Garren et al. (US Patent 5,178,877).

The teaching of Rouffer are discussed above and applied in the same manner.

Rouffer does not disclose the use of glycine, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT) or purified water as components in his gelatin capsule.

Garren discloses "pharmaceutically acceptable solvents for use in the soft elastic capsule composition are polyethylene glycol having molecular weight of from about 200 to about 600, propylene glycol, vegetable oils, polysorbate 80 or glycerin. The composition of the invention can also comprise various additives such as co solvents (for example, water, ethanol or propylene glycol), antioxidants (for example, BHT, BHA, propylgallate or alpha-tocopherol), stabilizing agents (for example, glycerin), solubilizing agents, flavoring agents, opacifiers (for example, titanium dioxide and the like) or coloring agents. In addition, the composition can comprise a plasticizer (for example, glycerin, sorbitol or propylene glycol) (column 2, line 54 through column 3, line 3).

The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed *prima Facie* obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of the soft gelatin capsule composition, to prepare a delivery system with

the desired dissolution profiles because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as a whole has been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Claim 9 and 21-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rouffer (US Patent 6,221,391) in view of Garren et al. (US Patent 5,178,877) and Adesunloye et al. (US Patent 5,874,106).

The teachings of Rouffer and Garren are discussed above and applied in the same manner.

Rouffer and Garren do not disclose the addition of citric acid in the soft gelatin capsule formulation.

Adesunloye discloses a method of reducing crosslinking in gelatin capsules wherein an amino acid and a carboxylic acid are incorporated (abstract). Glycine and citric acid are disclosed as the preferred amino acid and carboxylic acid, respectively (column 4, line 25).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have combined the teachings of Rouffer, Garren, and Adesunloye to form a stable gelatin capsules since Adesunloye discloses "the amino acid is believed to function by acting as a carbonyl scavenger, especially a formaldehyde scavenger, although the ability of an amino acid to function as both an

Art Unit: 1615

acid and a base may also contribute to its utility. The carboxylic acid is believed to facilitate the complete solubility of the amino acid in water and to stabilize the pH of the capsule fill" (column 3, lines 34-39).

One of ordinary skill in the art would have a reasonable expectation of success since all references teach a soft gelatin capsule with similar properties of the instantly claimed capsule.

The instant claims differ from the references only in the specific percentage selected for the compositions. However, It would have been deemed prima Facie obvious to one having ordinary skill in the art at the time of the invention to optimize the percentage of the soft gelatin capsule composition, to prepare a delivery system with the desired dissolution profiles because the determination of a specific percentage having the optimum therapeutic effect is well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the active compounds. Therefore, the invention as Whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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